

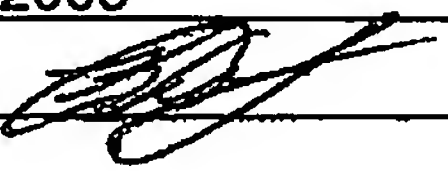
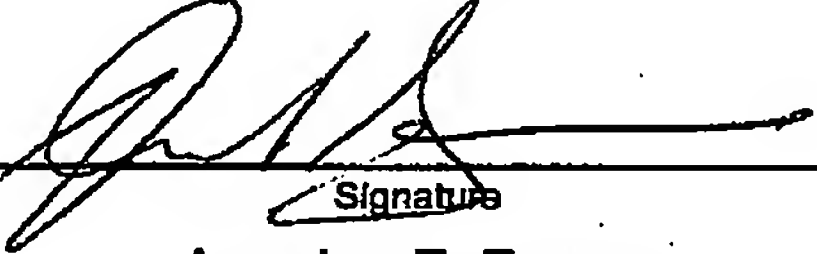
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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>101.0058-03000</b>	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>July 8, 2008</u></p> <p>Signature <u></u></p> <p>Typed or printed name <u>David M. Kogan</u></p>		Application Number <b>10/802,906</b>	Filed <b>March 17, 2004</b>
		First Named Inventor <b>Gary K. Michelson</b>	
		Art Unit <b>3733</b>	Examiner <b>Richard R. Shaffer</b>
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>37,129</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p> Signature <b>Amedeo F. Ferraro</b> Typed or printed name</p> <p><b>(310) 286-9800</b> Telephone number</p> <p><b>July 8, 2008</b> Date</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>			

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RESPONSE UNDER 37 C.F.R. 1.116  
 EXPEDITED PROCEDURE  
 EXAMINING GROUP 3733

PATENT  
 Attorney Docket No. 101.0058-03000  
 Customer No. 22882

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Confirmation No.: 5309
Gary K. Michelson	)	
Serial No.: 10/802,906	)	Group Art Unit: 3733
Filed: March 17, 2004	)	Examiner: Richard R. Shaffer
For: ORTHOPEDIC IMPLANT WITH	)	
LOCKING ELEMENT (as amended)	)	

Mail Stop AF  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

In reply to the Advisory Action of June 26, 2008 and the Final Office Action of April 8, 2008 ("Final Action"), Applicant submits the following remarks for consideration by the Members of the Pre-Appeal Brief Conference.

**I. Brief Background**

The present application includes three independent claims, claims 7, 42, and 47, generally drawn to an orthopedic implant for engaging at least one non-vertebral bone of the human body. Claims 7-51 are rejected under 35 U.S.C. § 112, first paragraph. Claims 7-10, 13-16, and 18-51 are rejected under 35 U.S.C. § 103(a). Claims 7-51 are rejected on the ground of nonstatutory obviousness-type double patenting. Claims 7-51 also are provisionally rejected on the ground of nonstatutory obviousness-type double patenting. Only the rejections under 35 U.S.C. § 112, first paragraph, and 35 U.S.C. § 103(a) are the subject of this Request for a Pre-Appeal Conference.

**II. Clear Errors**

**(1) The Examiner's rejection of claims 7-51 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.**

Independent claim 7 recites a "locking element being moveable without deformation from an initial position that permits the insertion of at least one bone screw into said bone screw receiving holes to a final position that retains at least two bone screws to said implant." Independent claim 42 recites "a non-elastic locking element for locking at least two bone

Pre-appeal Brief Request for Review.doc

Application No. 10/802,908  
Pre-Appeal Brief Request For Review July 8, 2008  
Reply to Final Office Action of April 8, 2008

screws inserted in said at least two bone screw receiving holes." Independent claim 47 recites "at least a portion of said locking element being adapted to cover at least a portion of at least one of said bone screw receiving holes and being rigid."

Regarding Independent claim 7, the Examiner contends that "there is no disclosure as originally filed stating that deformation does not take place (at least to some degree) especially in the stated possibilities of the base of the locking element acting as a cam." (Final Action, page 2, lines 18-20.) Regarding independent claims 42 and 47, the Examiner contends that "there is no disclosure defining the elasticity of the locking element in order to use terminology such as elastic, non-elastic, rigid, etc." (Final Action, page 3, lines 2-3.) Applicant submits that contrary to the Examiner's contentions, independent claims 7, 42, and 47 are fully supported in the specification so as to reasonably convey the claimed invention to one skilled in the relevant art that the Applicant, at the time the application was filed, had possession of the claimed invention.

Applicant's specification discloses that "[t]he plate and its component parts, may be made of any implant quality material suitable for this purpose and suitable for use in the human body, such as, but not limited to, titanium or its alloys." (Specification, page 4, lines 17-19.) Accordingly, because the locking elements are component parts of plates (or implants as recited in independent claims 7, 42, and 47), Applicant's specification discloses that the locking elements can be made of titanium or its alloys.

Applicant's specification discloses various embodiments of the locking elements. For example, the specification discloses an embodiment of a locking element (e.g., 20) that is "rotated in the clockwise direction" to "positively lock the associated bone screws 30" in place. (Specification, page 22, lines 22-26; and FIG. 11.) The specification further discloses "embodiments of locking elements 20a-20d" which "may be rotated in the direction of arrow A to bear upon at least a portion of the screw head to lock the bone screws to the plate." (Specification, page 25, lines 15-20; and FIGS. 31A-31D.) The specification also discloses an embodiment of a locking element where "the locking element head 23 can be provided with two slits 42 for providing flexibility to the locking element head 23 to assist in the locking element's ability to ride over the top of the bone screw head 32 during the locking action when the locking element is rotated." (Specification, page 22, lines 18-21; FIG. 16.) As such, the slits 42 are provided to afford flexibility of the locking element head 23, and, in doing so, allow

Application No. 10/802,906  
Pre-Appeal Brief Request For Review July 8, 2008  
Reply to Final Office Action of April 8, 2008

the associated locking element to deform when moved from an initial position to a final position. Hence, the locking elements without the slits 42 (such as the locking elements 20 and 20a-20d) are not flexible, and, necessarily, would move without deformation from the initial position to the final position. Thus, Applicant submits that the specification discloses locking elements that are non-deformable, non-elastic, and/or rigid.

Given that Applicant's specification discloses locking elements that can be made of titanium or its alloys, and that can be non-deformable, non-elastic, and/or rigid, independent claims 7, 42, and 47 are fully supported by Applicant's disclosure. Thus, the Examiner's rejection of claims 7-51 under 35 U.S.C. § 112, first paragraph, cannot be maintained.

**(2) The Examiner's rejections of claims 7-10, 13-16, and 18-51 under 35 U.S.C. § 103(a) over U.S. Patent No. 2,825,329 to Caesar ("Caesar") and claims 7-41 under 35 U.S.C. § 103(a) over U.S. Patent No. 4,488,543 to Tornier ("Tornier").**

Under Graham v. John Deere, recently reaffirmed by the Supreme Court in KSR International Co. v. Teleflex Inc. et al., 127 S.Ct. 1727 (2007), a combination of references that does not teach or suggest each and every element of the claimed invention, or references that teach away from the claimed invention support a finding of nonobviousness. As discussed below, Caesar and Tornier both do not teach each and every element, and, in fact, teach away from the claimed invention.

Independent claims 7, 42, and 47 each recite a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes." The Examiner contends that a sterile package containing plates 140 and 150 of Caesar "in effect would 'couple' the elements together prior to surgery." (Final Action, page 4, lines 3-8.) Merriam-Webster's Online Dictionary defines "couple" as "to connect for consideration together" and "to fasten together." (See <http://www.merriam-webster.com/dictionary/couple>.) Applicant submits that placing a plate and a locking element into a sterile package does not "connect" nor "fasten together" the plate and the locking element. Furthermore, as discussed below, Caesar and Tornier do not teach or suggest a locking element being coupled to the implant prior to the insertion of the bone screws.

**(a) Independent claims 7, 42, and 47 are patentable over Caesar under 35 U.S.C. §103(a).**

Caesar discloses a second plate 150 attached to a plate 140 using bone screws 158 during surgery. To attach the second plate 150 and the plate 140 to one another, the bone



Application No. 10/802,906  
Pre-Appeal Brief Request For Review July 8, 2008  
Reply to Final Office Action of April 8, 2008

screws 158 are first inserted into openings 156 in the second plate 150, then inserted into openings 70a and 72a formed in a bone, and, thereafter, received in openings 146 formed in the plate 140. (See Caesar, col. 3, lines 7-19; and FIG. 1.) Accordingly, Applicant submits that the second plate 150 and the plate 140 are attached to one another as a result of, not prior to, the insertion of the bone screws 158 into the openings 156 of the second plate 150 and the openings 146 of the plate 140. As such, unlike independent claims 7, 42, and 47, Caesar does not teach or suggest a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes," as recited in independent claims 7, 42, and 47.

Furthermore, Applicant submits that Caesar actually teaches away from the claimed invention as recited in independent claims 7, 42, and 47. As discussed above, the second plate 150 is attached to the plate 140 only after bone screws 158 are inserted into the openings 156 of the second plate 150 and into the openings 146 of the plate 140. Since Caesar expressly teaches that plate 150 is attached to plate 140 using the bone screws 158, Caesar teaches away from coupling a locking element to an implant prior to the insertion of the bone screws into the bone screw receiving holes. Since Caesar does not teach or suggest each and every element, and, in fact, teaches away from the claimed invention, Applicant submits that the Examiner's rejection of independent claims 7, 42, and 47 based on Caesar cannot be maintained.

**(b) Independent claim 7 is patentable over Tornier under 35 U.S.C. § 103(a).**

Tornier teaches a disc 11 that "has centrally between the three holes a diameter which partially covers each of heads 3a of screws 3 to assure their being held in corresponding holes 6." (Tornier, col. 2, lines 37-40.) Since the disc 11 covers the heads 3a of the screws 3, Applicant submits that the disc 11 of Tornier is attached to the plate 2 after the insertion of the bone screws 3 into the bone screw receiving holes 6. Tornier also teaches that the disk 11 "is elastic thereby making possible the passage of heads 3a of screws 3 and the backward movements of the screws 3, in the event that they come in contact with the cortical of the femoral head." (Tornier, col. 2, lines 44-48.)

Independent claim 7 recites a locking element "being coupled to said implant prior to the insertion of the bone screws into the bone screw receiving holes." Independent claim 7 also recites a locking element "being moveable without deformation from an initial position that

Application No. 10/802,906  
Pre-Appeal Brief Request For Review July 8, 2008  
Reply to Final Office Action of April 8, 2008

permits the insertion of at least one bone screw into said bone screw receiving holes to a final position that retains at least two bone screws to said implant." Given that the disc 11 of Tornier is coupled to the plate 2 after the insertion of the screws 3 into the bone screw receiving holes 6 and that the disc 11 is elastic, Tornier (unlike independent claim 7) does not teach or suggest both (1) coupling a locking element to an implant prior to the insertion of the bone screws into the bone screw receiving holes and (2) moving a locking element without deformation from an initial position that permits the insertion of at least one bone screw into the bone screw receiving holes to a final position that retains at least two bone screws to the implant. Since the disc 11 is coupled to the plate 2 after the insertion of the bone screws 3 into the bone screw receiving holes 6, Tornier, like Caesar, actually teaches away from the claimed invention of independent claim 7. Since Caesar does not teach or suggest each and every element, and, in fact, teaches away from the claimed invention, Applicant submits that the Examiner's rejection of independent claim 7 based on Tornier cannot be maintained.

### III. Conclusion

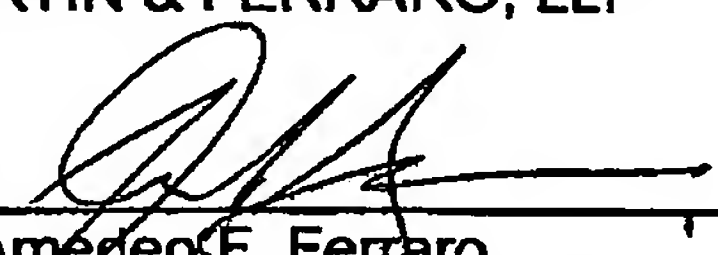
In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Members of the Pre-Appeal Brief Conference reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: July 8, 2008

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